

REMARKS

Applicants note that the amendments hereinabove are presented in the Revised Format of Amendments as described in the Flyer from the USPTO dated 2/13/03.

Claims 1-25 are pending in the instant application. The Examiner has required a restriction of the claimed invention under 35 U.S.C. 121 from the following groups:

- I. Claims 1-13, drawn to a conjugate of the Formula I.
- II. Claims 14-17, drawn to a method for treating prostate cancer comprising administering a conjugate of Formula 1.
- III. Claim 19, drawn to a method of making a pharmaceutical composition comprising a conjugate of Formula I.
- IV. Claims 20-23, drawn to a compound of formula II.
- V. Claims 24-25, drawn to a method for treating cancer by using a composition comprising a compound of Formula II.

The Examiner suggests that the inventions of Groups I and II-III are distinct one from the other because the two sets of invention groups are directed to products and processes of use. The Examiner suggests that the products claimed in Group I can be used in a materially different process of using, in particular as components for immunoassays, as molecular weight markers and in antibody production. The Examiner provides no specific examples of the use of the conjugates, or other peptide/cytotoxic agent conjugates, in such other processes. Applicant respectfully traverses the Restriction Requirement with respect to Groups I and II-III and requests reconsideration of the application with respect to those claims.

The Examiner also suggests that the inventions of Groups I-III and IV-V are distinct one from the other because each invention claimed in those claims is drawn to distinct compounds

having their own distinct and different structures, different mode of operation and different bioactivity and reactivity.

Applicant initially notes that she has cancelled Claims 20-25, without prejudice to filing a divisional application directed to the compounds and methods claimed therein. Therefore, the Restriction Requirement with respect to those claims (Groups IV-V) has been rendered moot and should be withdrawn.

The Examiner suggests that the inventions of Groups I and II-III are distinct as shown by their different classification and a search for such patentably distinct groups would not be co-extensive.

However, Applicant respectfully contends that a search of the prior art directed to the compounds claimed in Group I would not be an undue burden on the Examiner and would also clearly encompass all of the previously disclosed uses of such conjugates (if such uses were previously known). Applicant notes that numerous searches in the prior art have been performed related to cytotoxic agents conjugated (optionally through a linker) to a peptide and such searches have not resulted in unduly extensive citation. Applicant contends that such a search directed to the conjugate compounds themselves would also identify any prior art related to the methods of using those conjugates, either for the treatment of cancer, prostate cancer or BPH. Applicant also respectfully contends that the further requirement that the cytotoxic agent and peptide are attached via a hydroxyalkylamine will impose a further restriction on the scope of the search, thereby making such a search even less of an undue burden, yet the search would be comprehensive for all of Groups I-III described by the Examiner. MPEP 803 provides:

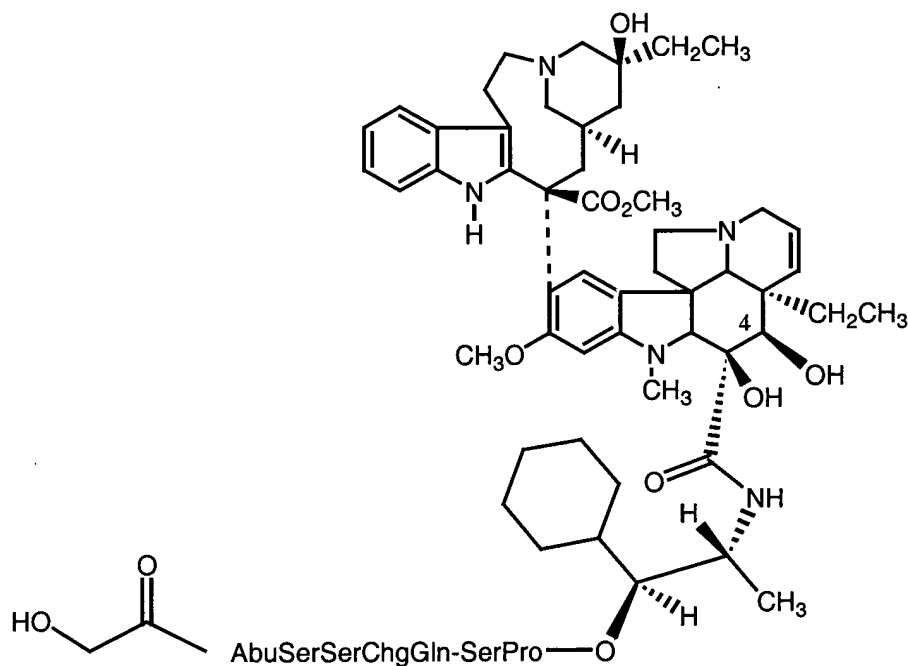
There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent or distinct as claimed; and
- (2) There must be a serious burden on the examiner if restriction is not required.

Because there would be no serious burden on the Examiner in searching such closely related inventions as are set forth by the Examiner, Applicant respectfully contends that the restriction requirement is improper.

Despite the Applicants contention that the Restriction Requirement is improper, Applicant respectfully elects Group I for examination, with traverse.

Applicant is required to elect a single disclosed species with a corresponding chemical structure for prosecution on the merits. Applicants hereby elect, with traverse, as a species the compound of Claim 10 as originally filed (which also appears in the specification at page 32), having the following structure:



Applicants respectfully contend that Claims 1-19 as filed are allowable and an early Notice of Allowance is earnestly solicited. If a telephonic communication with Applicants' representative will aid in the advancement of the prosecution of this application, please telephone the representative indicated below.

Respectfully submitted,

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